

Job description

Job title	Development Project Manager
Division	Development
Career Level	3
Responsible to	Head of Development

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized life-science company performing a range development and manufacturing roles for biopharmaceuticals. This also includes all associated support functions from logistics through to engineering, quality control / quality assurance, regulatory affairs and management. The Company manufactures two licensed products, Erwinase[®] and the UK's Anthrax Vaccine as well as providing R&D services for product development.

JOB SUMMARY

To provide active management of Development projects (including timelines, budget and cost, and deliverables) both internal and external, with responsibility for ensuring all aspects of project delivery for both PBL and its customers.

Communication and key working relationships

- Development managers and staff
- Commercial and business development
- Directors
- Regulatory
- Purchasing department
- Finance
- Production
- Engineering
- Presentations to all levels of personnel

External

- Contract Manufacturing Organisations
- Contract Research Organisation
- Consultants (e.g., clinical and pre-clinical)
- Existing and any new potential customers to the organisation
- Pharmaceutical community

MAIN DUTIES AND RESPONSIBILITIES

- Provide active management of a portfolio of assigned development-related projects and to have prime responsibility for operational liaison with project customers, both internal and external, to ensure completion of projects to high standards and to develop PBLs reputation and relationships. To include, but not be limited to, internal and external projects on biopharmaceutical products (vaccines & therapeutics), technology transfer internally and externally, management and oversight of CMOs and CROs, & internal and external process development.
- Responsible for setting, managing and keeping current all project timelines and ensuring that deliverables are met according to timelines, and communication is maintained with all stakeholders kept informed.
- Responsible for evaluation of assigned external and internal project enquiries for development activities to negotiate and finalise project definition, formulate proposals for resources and programmes required for project delivery.
- To be focal point for all project communication, ensuring project sponsors, stakeholders and team members kept appropriately informed. To communicate highly complex, sensitive and contentious information whilst overcoming barriers to understanding. Routinely reporting to line manager monthly and where appropriate, more often. Formal presentations to various groups internal and external, including executive management are expected. Ongoing liaison with research, development and regulatory groups is also an element of the role.
- Establish, in conjunction with line management, operational project teams. To provide leadership, manage relationships and motivate the teams throughout the project life cycle. Ensure that the membership of the project team is appropriate cross-functionally and is routinely reviewed and revised where needed. The project manager will agree activities, delivery dates, set the priorities for the team and address conflicts. Project manager would organise review of data and lead analysis and interpretation including making final decision where required.
- Establish and set budgets for operational projects as part of the annual budgeting process and as appropriate. To capture and manage changes to scope and costs to ensure projects operate within agreed margins. As budget owner management of budgets including periodic review of actual cost against budget with review of significant discrepancies. Interrogation and analysis of budgets with the view to drive costs down without unknown adverse effects on product quality or delivery.
- Develop and maintain detailed plans to assure efficient delivery of complex projects. Ensure project risk register is in place in the approved format and in a timely manner. Develop contingency plans as appropriate and communicate risk. Organise project management and review systems and as problems arise ensure rapid and effective resolution through the project teams or through escalation up departmental line management.
- Support Commercial function in developing and managing the CRO/CMO relationship pre-contract, activities include CRO/CMO liaison, assistance in negotiation, prompt delivery of information to the receiving organization and reciprocally back to PBL as needed. Effective management of other functions to obtain information usually against tight deadlines is a feature.
- Post contract signature full professional customer/contractor management acting as the primary customer/contractor (e.g., CMO) interface ensuring delivery against plan or in case of problems effective communication.

- Undertake all assigned work in accordance with the PBL Risk Management Systems, policies and procedures. Implement safety policies across the project functions not limited to but including the coordination safety check list which addresses HSE requirements for safety risk assessments and standard protocols for each project.
- Conduct quality reviews of projects to identify best practice and improvement areas to be addressed. Apply continuous improvement to improve the operational performance. Provision of project specific KPIs and other required metrics as required.
- Contribute to and if requested liaise with other PBL project managers on the delivery of wider PBL projects and high level scheduling of the entire PBL portfolio.
- Manage contract organisations to ensure product quality and high service level. Management and facilitation of audits and communication between the two organisations is a key component of this.
- Act as an internal project champion and customer for a specified product(s) or application(s) and maintain current understanding of ;
 - The production processes and associated analysis
 - Production and testing costs
 - The regulatory environment and impact on the product
 - The product application
 - The market place and understanding of risks to income
 - Competitor activities
 - Potentially competing technologies/patents
 - Seek potential collaborations to enhance income/efficiency or cost reductions
 - Work to schedule product manufacturing to free capacity for 1) additional new work 2) cross staff working
 - Initiate and prioritise margin improving projects
- In line with overall responsibilities, to perform any other tasks assigned or objectives set by the line manager.

Other

- The above is only an outline of the tasks, responsibilities and outcomes required of the role. You will carry out any other duties as may reasonably be required by your line manager.
- The job description and person specification may be reviewed on an ongoing basis in accordance with the changing needs of PBL.
- It should be noted that the work of the division is of a confidential nature and must not be communicated to other persons except where required for authorised purposes.

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Professional development

You should pursue a programme of continuous professional development in accordance with any relevant professional registration or statutory requirements, while maintaining appropriate awareness of service provider requirements.

You should adhere PBL values and behaviors:

- Passion
- Respect
- Integrity
- Diligence
- Excellence in Execution (E²)

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	<input checked="" type="checkbox"/>	
A good standard of written and spoken English Language	<input checked="" type="checkbox"/>	
Qualification		
BSc in Biological or Chemical Science or Graduate with extensive project and line management experience in regulated manufacturing.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
MSc in Biological or Chemical Science	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Management studies	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Business Studies	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Knowledge and experience Experience as defined by type/level (not length)		
<ul style="list-style-type: none"> Project Management involving outsourcing of complex biopharmaceutical projects Operational Management within a regulated environment Budget management Team Leadership 	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Pharmaceutical Product Development GMP manufacture Financial Management Computer skills for planning and budget control Change management within a regulated environment. Management of CMOs and CROs with experience of biopharmaceutical manufacture, nonclinical and clinical aspects 	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Skills and capabilities		
<ul style="list-style-type: none"> Planning and Project Management Continuous improvement Team Leadership Flexible approach Enthusiasm Goal orientation Energetic	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Personal effectiveness Corporate awareness Creative thinking	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Equality and diversity		
An understanding of and commitment to equality of opportunity and good working relationships, both in terms of day-to-day working practices, but also in relation to management systems	<input checked="" type="checkbox"/>	

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	